DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
93675d

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (714) 798-7600

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

October 9, 2001 W/L 05-02

Thomas T. Tierney, President
Vitatech International, Inc.
2832 Dow Avenue
Tustin, CA 92780

Dear Mr. Tierney:

During an inspection of your Tustin, California drug manufacturing firm conducted July 24-26, August 1-2, and September 7, 2001, our investigator documented serious deviations from Current Good Manufacturing Practice Regulations (CGMPs) found in Title 21of the Code of Federal Regulations, parts 210 & 211 (21 CFR § 210 & 211). These deviations cause your drug products to be adulterated within the meaning of Section 501 (a) (2) (B) of the Federal Food, Drug, and Cosmetic Act (the Act). For example:

1. Failure to assure equipment used in the manufacture, processing, packing, or holding of a drug product shall be of appropriate design, adequate size, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance [Ref: 21 CFR § 211.63]. Specifically, the reverse osmosis/deionized water system is not adequately validated. For example,

   - there is no written, approved, and completed validation protocol
   - out-of-specification results were obtained during the attempted validation and not investigated.

2. Failure to assure that automatic, mechanical, electronic, or other equipment used in the manufacture, processing, packing and holding of a drug product, performs or functions satisfactorily [Ref: 21 CFR § 211.68]. Specifically, the periodic monitoring procedures for the reverse osmosis/deionized water system are deficient. For example,

   - there is no justification to support the frequency of testing at the [redacted] sampling points
   - there is no procedure for the preparation and transport of the water samples to an outside laboratory for testing

- water sampling does not simulate water production use in that the sampling point is sprayed with isopropyl alcohol and flushed for one minute
- there are no investigations of out-of-specification readings obtained
- there are no written specifications for the daily monitoring of the reverse osmosis/deionized water system to include pressure differentials, resistivity and flow rates
- the daily monitoring logs of the reverse osmosis/deionized water system are not periodically reviewed by quality assurance personnel for completeness and accuracy and to ensure that the system meets specifications

3. Failure to assure equipment and utensils are cleaned, maintained, and sanitized at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond established requirements [Ref: 21 CFR § 211.67]. Specifically,

   a) there is no validation of the annual cleaning and sanitizing of the reverse osmosis/deionized water system conducted by an outside service contractor

   b) the cleaning validation studies for non-dedicated process equipment are deficient or lacking. For example,

      - there is no written and approved validation protocol
      - the cleaning validation consisted of only a swab sample from process equipment and analyzed for microbial bioburden
      - there are no specifications or justifications for swab sample locations
      - not all process equipment and utensils are included in the cleaning validation
      - there is no written and approved final validation report

4. Failure to establish a written procedure for production and process control designed to assure that the drug products have the identity, strength, quality and purity they purport or are represented to possess [Ref: 21 CFR § 211.100]. Specifically,

   a) there is no process validation completed for manufactured and distributed drugs (e.g. Formula Numbers [redacted]

   b) the master validation plan is deficient or lacking. For example,

      - it does not include process validation, cleaning validation and laboratory equipment validations
      - the master validation plan was initiated on 1/22/96 with no current updates
      - the HVAC, dust control collection, computer [redacted] and compressed air systems and utilities were not qualified as specified in the master validation plan

The above-described violations are not intended to be an all-inclusive list of those existing at your firm. It is your responsibility to ensure that all requirements of the Act and promulgated regulations are being met.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes, but is not limited to, seizure and/or injunction. Federal agencies are advised of the issuance of all warning letters involving drugs so that they may take this information into account when considering the award of contracts.

You should also notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you plan to take to assure that each of the noted violations will be corrected. Your response should also include an explanation of the specific steps that will be taken to prevent the recurrence of similar violations.

Your written reply should be addressed to:

Thomas L. Sawyer, Director of Compliance
U.S, Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, CA 92612

Sincerely,

Alonza Cruse
District Director

cc: California Department of Health Services, Food & Drug Branch
601 N. 7th Street
Sacramento, California 94234-7320
Attn: Stuart Richardson, Jr., Chief